

Structured Product Labeling (SPL) OTC Sub-team Teleconference
March 8, 2010, 1:00 – 2:00 pm ET
Call Summary

I. Call Attendees (based on emails received)

Attendance is based on email replies received. Call participants who are not listed below but were on the call (or you are listed and were not on the call) should notify Marcia Howard.

-  Cheryl Blik, Teva Pharmaceuticals, Inc.
-  David Brown, Colgate Palmolive Company
-  Terry Brunone, GlaxoSmithKline
-  Gail Burke, Procter & Gamble
-  Lisa Fields, Blistex, Inc.
-  Chris Guay, Procter & Gamble
-  Michele Hewitt, Sandoz, Inc., Broomfield
-  Maureen Kapustynski, Cadbury
-  Mike Koenig, FDA
-  Juris Lazdins, Novartis Consumer Health, Inc.
-  Paula Markert, GlaxoSmithKline (sub-team leader)
-  Kathryn Moreng, Bayer Consumer HealthCare
-  Diane O'Grady, Purdue Pharma L.P.
-  Alison Rago, Intagras
-  Janet Riffitts, McNeil Consumer Healthcare
-  Eva Rivera, Glemser Technologies Corporation
-  Gary Saner, Reed Technology & Information Services, Inc.
-  Dave Schilling, Chattem, Inc.
-  Howard Shatz, Data Conversion Laboratory, Inc.
-  Siobhan Stevens-Miles, Merck & Co., Inc.
-  Carl Strotz, Pfizer Consumer Healthcare
-  Beth Thompson, Medline Industries, Inc.
-  Craig Trautman, Intagras
-  Karen Vescovi, Church & Dwight Co., Inc.
-  Ann Vu, FDA
-  Elise Wolf, Combe Incorporated
-  Barbara Wolfe, Pfizer Consumer Healthcare
-  Marcia Howard, CHPA staff (sub-team liaison)

II. Next Standing Teleconference: April 12, 2010, 1:00pm ET (unless cancelled)

III. FDA Indexing Initiative

- ✚ Terry Brunone (GSK; SPL Working Group co-leader) gave an overview on indexing as FDA has requested stakeholder input on its next indexing activities and priorities for medical conditions (see slide deck provided separately). Thanks were extended to Terry for her excellent presentation and background information provided.
- ✚ Initial discussion about the indexing activity included the following points (listed in random order):
 - FDA should consider starting with monograph products as the class language is prescribed in the regulations.
 - The initiative seems counterproductive.
 - There are liability concerns if there are errors.
- ✚ A sub-team organized under the SPL Leadership Team is currently working on a proposal for an FDA public workshop to explain the initiative to stakeholders so interested parties can then provide informed feedback to the agency.
- ✚ A working group from the SPL OTC Sub-team will be created to outline any feedback submitted on behalf of the group. All interested sub-team members should provide comments/feedback/input to Marcia Howard at their earliest convenience. Updates on the working group will be sent to the full sub-team as appropriate. The following persons have volunteered to be a part of the working group thus far (as of March 16, 2010):
 - Chris Guay, Procter & Gamble
 - Paula Markert, GlaxoSmithKline
 - Barbara Wolfe, Pfizer Consumer Healthcare
 - Marcia Howard, CHPA staff

IV. Posting of OTC Monograph Drug Listing Information to DailyMed

- ✚ At this time, FDA has no immediate plans to make drug listing information on monograph OTC products publicly available via DailyMed.
- ✚ The information is available via “Freedom of Information Act” (FOIA) request to anyone who is interested in receiving the information. Requests can be submitted to FDA via procedures outline on the agency’s website (<http://www.fda.gov/RegulatoryInformation/FOI/HowtoMakeaFOIARequest/default.htm>).
- ✚ The number of FOIA requests is often an indicator of stakeholder interest specific FDA information. Depending on the number and frequency of the

requests, the agency could re-evaluate whether or not it is more efficient to provide the information proactively vs. responding to individual requests.

V. Upcoming SPL Educational Forums/Information (*For Your Information*)

FDA SPL R4 Training Sessions – Please visit website for updated information regarding training courses.

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm155705.htm>

- A. **FDA Training Sessions:** Monday webinars at 10:00 am ET and Q&A sessions at 11:30 am ET (same for both; cancelled for Federal holidays or as necessary)

Telephone number: 1-866-775-9435

Participant pass code: 5753366

Registration Information for Web Training Sessions only (registration not required for public Q&A sessions)

There is no registration fee for the training sessions but pre-registration is required because of limited connections for the webinars. To register, please submit the following information via e-mail to spl@fda.hhs.gov:

1. Attendee's first and last name
2. Name of your organization
3. Session name and date of training session(s) for which you are registering.

You will be limited to one phone/web conference line per company.

For further information, contact: spl@fda.hhs.gov.

For the 2010 SPL Training Sessions schedule, visit <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm155705.htm>.

FDA has released a series of e-Training Books and Cards that are available on the SPL Wiki page as another SPL resource to industry.
(<http://spl-work-group.wikispaces.com/>)

- B. **SPL Process Communication Forum (Process Team):** Alternating Wednesdays 1:00 - 2:30 pm ET (unless cancelled; opposite to ERDL calls)
Telephone number: 877-423-2663
PIN#: 558089
Please email Process Team co-leaders Terry Brunone (Theresa.M.Brunone@gsk.com) or Mary Beth Wilusz (mary_beth_wilusz@merck.com) if you want to receive the email information.
- C. **SPL ER/DL Sub-team calls:** Alternating Wednesdays at 1:00 pm ET (unless cancelled)
Telephone number: 866-217-3840
Conference Code: 4286445422
Please email sub-team leader Pat Cowall-Hanover if you want to receive the email information (COWALL-ANOVER PATRICIA L@LILLY.COM) .
- D. **SPL Generics Sub-team calls:** Currently not holding standing teleconferences
Please email sub-team leader Virginia Hogan if you want to receive the email information (Virginia.Hogan@tevausa.com).

MDH/03-16-10

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